## State of California DEPARTMENT OF JUSTICE



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August 23, 2000

By Overnight
Jennifer Butler
Docket Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE:

FDA Docket 00P-1210/CP1: Comments concerning Gottesfeld Petition for formal review of the conditions of sale, use and distribution of FDA-regulated products containing Coal Tar USP

Dear Ms. Butler:

I am writing on behalf of the Attorney General for the State of California in response to the August 8, 2000 letter of Carol Brophy, counsel for Bergen Brunswig Drug Company, commenting on the petition of Perry Gottesfeld, Docket No. 00P-1210/CP1.<sup>1</sup>

Ms. Brophy's letter discusses in great length a suit filed by the Attorney General in state court on behalf of the People of the State of California under Health & Safety Code section 25249.5 et seq. ("Proposition 65") against manufacturers of coal tar shampoos and skin care products. The Attorney General's lawsuit alleges that the manufacturers have exposed individuals to carcinogens listed under Proposition 65, including tars and various polyaromatic hydrocarbons (benzo(a)pyrene, benzo(a)anthracene, etc.) without providing a warning. Mr. Gottesfeld, the petitioner in Docket No. 00P-1210/CP1, filed a separate Proposition 65 lawsuit in state court against the manufacturers of the coal tar products in state court in his capacity as a private citizen; Mr. Gottesfeld's case was consolidated with the case filed by the Attorney General. The consolidated case is currently set to go to trial on October 10, 2000.

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<sup>&</sup>lt;sup>1</sup>This letter does not attempt to respond to all legal and factual inaccuracies contained in Ms. Brophy's letter.

Jennifer Butler August 23, 2000 Page 2

Contrary to Ms. Brophy's assertions, the Proposition 65 lawsuit now pending in state court has no direct relationship to or bearing on Gottesfeld petition now pending before the Food and Drug Administration ("FDA"). Ms. Brophy states at the bottom of page 2 and top of page 3 that the state court will decide whether pharmaceuticals containing Coal Tar USP are safe when used in concentrations authorized under the Coal Tar Monograph, or if limitations to the sale, use and distribution of such products are warranted. This is incorrect. Proposition 65 does not address the safety of the product, but simply mandates that businesses that expose individuals to listed carcinogens must provide a clear and reasonable warning. Thus, nothing decided by the state court will determine whether the product is safe and effective, a matter to be determined by the FDA. Furthermore, nothing in the state lawsuit will control the sale, use and distribution of the products. The products can remain on the market, if the manufacturers so choose, subject to the warning requirement.

Ms. Brophy further asks the FDA to adjudicate certain issues that are well beyond the scope of the Gottesfeld petition and beyond the regulatory authority of the FDA. For example, on page 5 of her letter, Ms. Brophy asks the FDA to determine whether coal tar USP is encompassed under the listing of soots, tars and mineral oils contained in Proposition 65. Ms. Brophy also asks the FDA to determine the average consumers' use of shampoos, soaps, and ointments, a determination to be made under Proposition 65 regulations. We respectfully request that the FDA reject Ms. Brophy's request and decline to rule on issues of state law.

In addition, Ms. Brophy asks the FDA to determine if the provision of the Proposition 65 warning on Coal Tar products would constitute "misbranding." In effect, Ms. Brophy requests a ruling on preemption of Proposition 65 by the FDA in the context of the Gottesfeld petition -- notwithstanding the fact that 21 U.S.C. section 379r(d)(2), a provision of the Food and Drug Administration Modernization Act, specifically states that laws such as Proposition 65 are not preempted.<sup>2</sup> While Ms. Brophy is free to pursue her preemption argument in the appropriate forum, e.g., state court,<sup>3</sup> we request that the FDA refrain from taking any position in conflict with Section 379r(d)(2) that would suggest that Proposition 65 warnings are preempted.

<sup>&</sup>lt;sup>2</sup>It is also our understanding that one of the manufacturers of the coal tar products has already approached FDA on this issue and has been told that the FDA does not intend to take a position that the Proposition 65 warning would constitute misbranding.

<sup>&</sup>lt;sup>3</sup>A motion for summary adjudication based on preemption is now pending in the state court action.

Jennifer Butler August 23, 2000 Page 3

If you have any questions concerning the above, or require additional information, please feel free to contact me.

Sincerely,

SUSAN S. FIERING

Deputy Attorney General

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